CHAPTER 61-02-01 ***REVISED DRAFT COPY***
PHARMACY PERMITS

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61-02-01-19 Continuous Quality Improvement

61-02-01-19-01 Definitions: In this chapter, unless the context or subject matter otherwise requires:

1. "Actively Reports" means reporting all dispensing errors and analysis of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

2. "Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

3. "Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

    a. Variation from the prescriber's prescription drug order, including, but not limited to:

        i. Incorrect drug;

        ii. Incorrect drug strength;

iii. Incorrect dosage form;

iv. Incorrect patient; or

v. Inadequate or incorrect packaging, labeling, or directions.

b. Failure to exercise professional judgment in identifying and managing:

i. Therapeutic duplication;

ii. Drug-disease contraindications, if known;

iii. Drug-drug interactions, if known;

iv. Incorrect drug dosage or duration of drug treatment; interactions;

v. A clinically significant, avoidable delay in therapy; or

vi. Any other significant, actual or potential problem with a patient's drug therapy.

c. Delivery of a drug to the incorrect patient.

d. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

i. Incorrect drug;

ii. Incorrect drug strength;

iii. Incorrect dosage form; or

iv. Inadequate or incorrect packaging or labeling.

4. "Incident" A patient safety event that reached the patient, whether or not the patient was harmed.

5. "Near Miss" A patient safety event that did not or could not have reached the patient.

6. "Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

7. "Unsafe Condition" Any circumstance that increases the probability of a patient safety event.

61-02-01-19-02 Continuous Quality Improvement Program

1. Each pharmacy permittee shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing incidents, near misses, and unsafe conditions.

2. A pharmacy permittee meets the requirements if they meet the following:

    a. Maintains and complies with the policies and procedures as noted in (4);

    b. The pharmacy reports incidents, near misses and unsafe events through either:

        i. a contracted Patient Safety Organization (PSO) that is listed as an Agency for Health Research and Quality (AHRQ) on www.ahrq.com whose primary mission is pharmacy continuous quality improvement; or.

        ii. an internal program to the pharmacy which is acceptable to the Board where proper documentation and evaluation can be completed

3. At a minimum, a CQI Program shall include provisions to:

    a. Designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

    b. Initiate documentation of incidents, near misses, and unsafe conditions as soon as possible, but no more than seven days, after determining their occurrence;

4. Policies and Procedures in compliance with 61-02-01-19 and must include.

    a. Train all pharmacy personnel in relevant phases of the CQI program;

    b. Identify and document reportable incidents and near misses and unsafe events;

    c. Minimize the impact of incidents and near misses and unsafe events on patients;

    d. Analyze data collected to assess the causes and any contributing factors relating to incidents and near misses and unsafe events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce incidents and near misses and unsafe events; and

f. Periodically, but at least quarterly, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

5. Quality Self-Audit

   a. Each Pharmacy shall conduct a Quality Self-Audit at least quarterly to determine whether the occurrence of incidents, near misses, and unsafe conditions has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program.

6. Protection from Discovery

   a. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.

   b. Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are confidential and shall not be released, distributed or communicated in any manner, except as provided by these rules or the permitee's policies and procedures. Recognizing the importance of sharing information with staff , experts, consultants, and others is necessary in reducing medication errors, information used as a part of the permitee's quality program in any manner shall not compromise the confidentiality and privilege of such information.

   c. This subsection does not prohibit a patient from accessing the patient's prescription records or affect the discoverability of any records that are not generated solely as a component of a pharmacy's ongoing quality assurance program and maintained solely for that program.

7. The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to inspection of the pharmacy's CQI policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

8. An analysis or summary of findings, produced within six months of submission, shall be evidence of compliance with the records and data collection provisions.

A permittee shall not be required to produce data, charts, error reports or findings collected and used in compiling an analysis summary.

9. Not withstanding paragraphs (6) and (8), If pharmacy is reporting to a Patient Safety Organization whose primary mission is continuous quality improvement all data and records are privileged and confidential as provided in the 2005 Patient Safety and Quality Improvement Act of 2005 and implementing regulations.

History: Effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10, 23-34
Law Implemented: NDCC 28-32-03, 43-15-10, 23-34

CHAPTER 61-03-01
LICENSURE OF PHARMACISTS

Section
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61-03-01-04. Licensure ~~without examination~~ transfer. An applicant seeking licensure by licensure transfer or reciprocity must secure and file an application blank from the national association of boards of pharmacy. This board will license applicants by reciprocity if they possess the requirements in effect in North Dakota at the time the candidates were licensed by examination in other states. ~~A statement from the executive director secretary under seal of the board of pharmacy from which the applicant is a licentiate, showing date of examination, qualification, detailed ratings, and general average, must be submitted.~~ The applicant must pass the North Dakota law examination and pay the appropriate fees to obtain licensure.

History: amended effective April 1, 2016
General Authority: NDCC 43-15-22
Law Implemented: NDCC 43-15-22

CHAPTER 61-04-08
LIMITED PRESCRIPTIVE PRACTICES

61-04-08-01. Purpose. The purpose of these rules is to implement limited prescriptive practices provisions of the North Dakota Century Code.

History: Effective December 1, 1996.
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-02. Definitions. For purposes of this chapter:

1. "Collaborative agreement" means the written document signed by a ~~physician~~ practitioner and a pharmacist which describes the limited prescribing authority granted the pharmacist under North Dakota Century Code section 43-15-31.4.

2. "Immediate notification" means interactive two-way communication between the pharmacist and ~~physician~~ practitioner within twenty-four hours of the initiation or modification of drug therapy, unless specific reference is made in the collaborative agreement to situations in which a notification time limit of up to seventy-two hours is appropriate.

3. "Initiate drug therapy" means to begin administering for the first time a prescribed drug therapy for treating a patient with an existing diagnosis. A licensed ~~physician~~ practitioner shall make any diagnosis required.

4. "Medical record" means a written record of clinical care developed and maintained by a patient's ~~physician~~ practitioner which contains information and data about a patient's condition sufficient to justify the diagnosis and subsequent treatment. The record must contain further appropriate information as described in section 33-07-01.1-20.

5. "Modify drug therapy" means to change, within the same therapeutic class of drugs, a specific drug, the dosage, or route of delivery of a drug currently being administered for an existing diagnosis.

~~6. "Pharmacist in an institutional setting" means a pharmacist who:~~

~~a. Has a written agreement to provide daily or regular pharmaceutical services within a hospital, physician clinic, skilled nursing facility, swing-bed facility, or long-term care facility; and~~
~~b. Is physically present in the facility when exercising prescriptive practices under the terms of a collaborative agreement.~~

6. "Practitioner" means a licensed physician or advanced practice registered nurse.

7. "Supervision" means the active role taken by the ~~physician~~ practitioner to oversee the pharmacist throughout the provision of drug therapy to patients under the terms of a collaborative agreement.

History: Effective December 1, 1996; amended effective December 1, 2003, amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-03. Eligibility and approval.

1. A ~~physician~~ practitioner and a pharmacist who are licensed and practicing their respective professions in this state are eligible, provided the conditions of this section and any applicable statutes are met, to enter into the collaborative agreement allowing the pharmacist to provide prescription drug therapy to patients ~~in an institutional setting on a limited basis~~.

2. The practitioner and the pharmacist must have access to the patient's appropriate medical records. The care provided to the patient by the pharmacist must be recorded in the patient's medical records and communicated to the practitioner.

~~2. A physician may have a collaborative agreement with no more than three eligible pharmacists unless the physician's licensing board specifies otherwise based on individual circumstances. A pharmacist may have a collaborative agreement with one or more physicians, the number of which may be limited by the board based on individual circumstances.~~

3. ~~The collaborative agreement serves as a formal arrangement between an individual pharmacist and an individual collaborative supervising physician and is operative only within the institutional setting identified on the collaborative agreement form.~~ The collaborative agreement may be between a medical director and pharmacist-in-charge. The medical director and pharmacist-in-charge shall report to the respective board of any practitioner and pharmacist covered under the agreement.

4. Each individual collaborative agreement must be reviewed by the board of ~~medical examiners~~ medicine or the board of nursing and the board of pharmacy, and will not become effective until ~~both~~ the respective boards grant approval and notify the parties. Each agreement must be reviewed at least every ~~two~~ four years or when modifications to the scope of the pharmacist's prescriptive practices are proposed by the parties, and must receive continued approval from both boards in order to remain in effect. Removal or addition of either practitioners or pharmacists involved in the agreement shall be communicated to all respective boards. Unless deemed necessary, a change in personnel does not necessitate board approval of the collaborative agreement.

5. A collaborative agreement may be terminated by ~~either~~ any of the involved boards for good cause, including adverse action taken against either licensee. Noncompliance with the terms of these rules or of a collaborative agreement may be considered evidence of unprofessional conduct by ~~either~~ any of the involved boards.

6. Either party of a collaborative agreement may terminate the agreement at will by notifying either board of their desire to do so.

7. Neither party to a collaborative agreement may seek to gain personal financial benefit by participating in any incentive-based program that influences or encourages therapeutic or product changes.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-04. Procedures. A ~~physician~~ practitioner who has signed an approved collaborative agreement with a pharmacist shall remain responsible for the care of the patient following initial diagnosis ~~and assessment~~, and for the supervision of the pharmacist as prescriptive authority is exercised. The ~~physician~~ practitioner shall remain available to receive immediate notification from the pharmacist regarding prescriptive drug therapy being provided. The parties may modify as necessary, within the practice guidelines described in the collaborative agreement, their relationship in the joint provision of care to each patient as the requirements of the patient or drug therapy change.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-05. Initiation of drug therapy. To initiate drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating ~~physician~~ practitioner. ~~A pharmacist may initiate drug therapy only if the pharmacist has obtained a doctor of science, doctor of philosophy in clinical pharmacy, master of science, or doctor of pharmacy degree, has been certified a~~

~~fellow by the board of pharmaceutical specialties, or has completed an accredited pharmacy fellowship or residency, and has been authorized to do so within the collaborative agreement. Verification of these credentials must be provided by the pharmacist.~~ The pharmacist must provide immediate notification to the ~~physician~~ practitioner when the pharmacist initiates drug therapy.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-06. Modification of drug therapy.

1. To modify drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating ~~physician~~ practitioner. A pharmacist may modify drug therapy as warranted to assure an appropriate course of treatment for the patient. The pharmacist must provide immediate notification to the ~~physician~~ practitioner when the pharmacist modifies drug therapy.

2. The ~~physician~~ practitioner and pharmacist entering into a collaborative agreement must have indicated on the form the scope and authority to be exercised by the pharmacist and the type or class of drugs or drug therapy to be utilized or prohibited under the agreement. Authority to prescribe schedule II drugs may not be delegated to a pharmacist. The parties may also indicate the type of medical diagnoses to be included or excluded within the collaborative relationship.

3. The current medical record of each patient receiving drug therapy must be readily accessible to the pharmacist and ~~physician~~ practitioner ~~within the facility setting~~. The pharmacist, unless ~~physician~~ the practitioner ~~or facility policy~~ directs otherwise, shall provide timely documentation and indications for all drug therapies initiated or modified by the pharmacist as part of the medical record.

4. Contingency treatment should be addressed for treating allergic or acute adverse drug reactions.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

61-04-08-07. Form.

1. The collaborative agreement form utilized under this section is attached as an appendix to these rules as approved by the board of ~~medical examiners~~ medicine, board or nursing, and board of pharmacy. Upon request, ~~either~~ a board shall supply a copy of the rules and form to any interested party.

2. A copy of each collaborative agreement and subsequent amendments approved by the boards shall remain on file with the boards. Each party shall retain the original or a copy of the agreement and amendments, and either party shall provide a copy to ~~the~~ a facility within which ~~the~~ an agreement is operative.

3. Either board may disseminate a current listing of the individual parties who are practicing under an approved collaborative agreement.

4. More details may be provided. Further stipulations or details shall be supplied on a separate page.

History: Effective December 1, 1996. amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4
Law Implemented: NDCC 28-32-02, 43-15-10(9)(12)(14), 43-15-31.4

APPENDIX

COLLABORATIVE AGREEMENT FORM

The pharmacists and ~~physicians~~ practitioners listed below are parties to this collaborative agreement, through which the pharmacist receives limited prescriptive authority under the supervision of the ~~physician~~ practitioner in accordance with North Dakota Century Code section 43.15-31.4 and administrative rules.

~~Institution~~Facility	Facility
Address	Address
Telephone	Telephone

Pharmacist Name	License Number	~~Physician~~ Practitioner Name	License Number
Pharmacist Name	License Number	~~Physician~~ Practitioner Name	License Number
Pharmacist Name	License Number	~~Physician~~ Practitioner Name	License Number
		~~Physician~~ Practitioner Name	License Number

[Please review the administrative rules governing collaborative agreements which accompany this form before proceeding.]

1. Describe the scope and authority to be exercised by the pharmacist. (If requesting authority to initiate drug therapy, pharmacist must include credential verification.)
2. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement. (Note: Schedule II drugs are excluded by these rules.)
3. If appropriate, indicate any diagnosis which are specifically included or excluded under this agreement.
4. Attach any protocols or guidelines to be used in decision making or other activities contemplated under this agreement. This must include a protocol for treating acute allergic or other adverse reactions related to drug therapy.
5. Describe approved situations, if any, in which the notification time limit may be extended beyond twenty-four hours (not to exceed seventy-two hours).

Attach additional sheets if necessary.

Pharmacist Signature	Date	~~Physician~~ Practitioner Signature	Date
Pharmacist Signature	Date	~~Physician~~ Practitioner Signature	Date
Pharmacist Signature	Date	~~Physician~~ Practitioner Signature	Date
		~~Physician~~ Practitioner Signature	Date
State Board of Pharmacy	Approval Date	State Board of ~~Medical Examiners~~ Medicine	Approval Date
		State Board of Nursing	Approval Date

CHAPTER 61-04-10
CLIA WAIVED LABORATORY TESTS

Section
61-04-10-01 Definitions
61-04-10-02 Education Requirements for Pharmacists to Perform CLIA Waived Laboratory Tests
61-04-10-03 Minimum Quality Standards Required
61-04-10-04 Proper CLIA Registration
61-04-10-05 Notification of the Board of Pharmacy
61-04-10-06 Exempt Tests and Methods

61-04-10-01. Definitions. For purposes of this chapter:

1. "CLIA" means the federal Clinical Laboratory Improvement Act of 1988, as amended.
2. "OSHA" means the federal occupational safety and health administration.
3. "Portfolio review" means a review by the board of a pharmacist's records of ~~proficiency testing~~ training logs, control testing logs, and records of patient tests performed to determine that a pharmacist is continuously and consistently providing a service in a quality and competent manner.

History: Effective December 1, 1999; amended effective July 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-02. Education requirements for pharmacists to perform CLIA waived laboratory tests. A pharmacist must meet the following requirements in order to perform CLIA waived laboratory tests authorized by North Dakota Century Code section 43-15-25.3 or added to the list as allowed by ~~that~~ section 61-04-10-06:

1. Successfully complete ~~a board-approved course of study~~ training and education that incorporates ~~principles of general laboratory procedures to include~~, at a minimum:
   a. Infection control;
   b. OSHA requirements;
   c. Proper technique to collect laboratory specimens;
   d. Recognized screening and monitoring values; and
   e. Quality control.
   f. The manufacturers' instructions for the waived tests being performed.
2. Obtain and recertify the CLIA waived certificate every ~~three~~ two years ~~by portfolio review or reeducation~~.
3. ~~Successfully complete training for each specific instrument used to perform CLIA waived laboratory tests.~~

History: Effective December 1, 1999; amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-03. Minimum quality standards required. Pharmacists performing CLIA waived laboratory tests must meet the following standards:

1. Develop and maintain a policy and procedure ~~procedural~~ manual that includes the following areas:
   a. Quality control;
   b. Infection control;
   c. Hazardous waste disposal;
   d. Recordkeeping; and
   e. Test result reporting.

~~2. Maintain participation in a nationally recognized proficiency program approved by the board.~~

History: Effective December 1, 1999; amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-04. Proper CLIA registration. The pharmacist-in-charge of a licensed pharmacy performing tests or any pharmacist operating in a facility not licensed by the board is responsible for ensuring that the pharmacy performing the CLIA waived test ~~facility where the tests are performed~~ has a proper CLIA certificate.

History: Effective December 1, 1999; amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-05. Notification of the board of pharmacy. The pharmacist-in-charge of a licensed pharmacy that has obtained a CLIA certificate or any pharmacist operating in a facility not licensed by the board of pharmacy must notify the board prior to the initial performance of any CLIA waived tests. ~~The notification must specify the types of tests which are to be performed.~~

History: Effective December 1, 1999; amended effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

61-04-10-06. Exempt tests and methods. An individual licensed by the board, performing the following food and drug administration-waived tests and using the following methods, is exempt from the provisions of North Dakota Century Code chapter 43-48:

1. Total cholesterol, HDL cholesterol, and triglycerides test by any accepted method
2. Any of the following tests by nonautomated or automated urinalysis by dipstick:
   a. Bilirubin.
   b. Blood.
   c. Glucose.
   d. Ketone.
   e. Leukocyte.
   f. Nitrate.
   g. Potential of hydrogen (pH).
   h. Protein.

i. Specifc gravity.
j. Urobilinogen.

3. Fecal occult blood by any accepted method.
4. Ovulation test by visual color comparison.
5. Qualitative urine pregnancy test by visual color comparison.
6. Erythrocyte sedimentation rate by any accepted nonautomated method.
7. Whole blood glucose by any accepted single analyte method.
8. Spun microhematocrit by any accepted method.
9. Hemoglobin by single analyte instrument or manual copper sulfate method.
11. Any of the following tests by immunoassay using a rapid test device that detects antibodies or antigens:
    a. Helicobacter pylori.
    b. Influenza.
    c. Mononucleosis.
    d. Streptococcus group A.
    e. Hepatitis C virus.
    f. Respiratory syncytial virus.
12. Prothrombin time international normalized ratio by mechanical endpoint.
13. Antibodies to human immunodefciency virus types 1 and 2.
14. Nicotine or cotinine test by any accepted method
15. Thyroid stimulating hormone blood test by any accepted method.
16. Vitamin D blood test by any accepted method
17. Bone mass and bone mineral density test by any accepted method
18. Genomic testing by any accepted method
19. Drug screening tests by any accepted method

History: Effective July 1, 2016
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 43-15-25.3

ARTICLE 61-04
PROFESSIONAL PRACTICE

CHAPTER 61-04-12
LIMITED PRESCRIPTIVE AUTHORITY FOR NALOXONE

61-04-12-01. Definitions. For purposes of this chapter:

1. "Opioid-related drug overdose" means a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid or another substance with which an opioid was combined. This would include an overdose that requires medical assistance or a coroner, clinical suspicion for drug overdose (respiratory depression, unconsciousness, altered mental status), and either a urine toxicology screen positive for opiates or negative urine toxicology screen without other conditions to explain the clinical condition.

2. "Patient" means both an individual who is at risk of opioid overdose and a person who is not as risk of opioid overdose but who may be in a position to assist another individual during an overdose and who has received patient information.

3. "Patient information" means the information provided to the patient on drug overdose prevention and recognition; opioid antidote dosage and administration; the importance of calling 911; care for the overdose victim after administration of the overdose antidote; and other issues as necessary.

61-04-12-02. Pharmacists Furnishing Naloxone.

1. Protocol.
   a. Pharmacists are authorized to furnish naloxone drug therapy solely in accordance with the written protocol for naloxone drug therapy approved by the board.
   b. Any pharmacist exercising prescriptive authority for naloxone drug therapy must maintain a current copy of the written protocol for naloxone drug therapy approved by the board.

2. Procedure. When a patient requests naloxone, or when a pharmacist in his or her professional judgement decides to advise of the availability and appropriateness of naloxone, the pharmacist shall complete the following steps:
   a. Screen for the following conditions:
      (1) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids (if yes, skip to item b and continue with procedure);

(2) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids (if yes, continue with procedure);

(3) Whether the person to whom the naloxone would be administered has a known hypersensitivity to naloxone (if yes, do not furnish).

b. Provide training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

c. When naloxone is furnished:

(1) The pharmacist shall provide the patient with appropriate patient information and counseling on the product furnished including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. A pharmacist furnishing naloxone drug therapy shall not permit the patient to whom the drug is furnished to waive the patient information required by the board.

(2) The pharmacist shall provide the patient with any resources and/or referrals to appropriate resources if the patient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(3) The pharmacist shall answer all questions the recipient may have regarding naloxone.

3. Authorized drug(s).

a. Prescriptive authority shall be limited to naloxone and shall include any device(s) approved for the administration of naloxone.

b. Those administering naloxone should choose the route of administration based on the formulation available, how well they can administer it, the setting, and local context.

4. Education and training. Prior to furnishing naloxone, pharmacists who participate in this protocol must successfully complete a minimum of one hour of an approved continuing education program specific to the use of naloxone, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

5. Records. The prescribing pharmacist must generate a written or electronic prescription for any naloxone dispensed and the pharmacist shall record themselves as the prescriber or the protocol practitioner if appropriate. Documentation shall be made in a medication record for the patient. The prescription shall be kept on file and maintained for 5 years as required in 43-15-31.

6. Notification. If the patient is the potential individual to whom the naloxone will be administered, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a record system shared with the primary care provider.

If the patient does not have a primary care provider, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

History: Effective July 1, 2016.
General Authority: NDCC 28-32-02, 43-15-10
Law Implemented: NDCC 23-01-42, 43-15-10 (23)